OCT 1 8 2000

K002957

510(k) Summary of Safety and Effectiveness

Date: October 13, 2000

Submitter: GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems, Inc.
Phone: (414) 362-2090
Fax: (414) 371-3736

Device: Trade Name: Solar SPO2 Module with Masimo SET

Common/Usual Name: Pulse Oximeter and sensor

Classification Names:
21 CFR 870.2700 Oximeter, Pulse
21 CFR 870.2900 Cables, Transducer and Electrode

Predicate Devices: K901071 Marquette Pulse Oximetry Module

K990966 Masimo SET® 2000 Pulse Oximeter and LNOP® series of sensors and cables

Device Description: The Solar SPO2 Module is part of a modular system that requires a connecting cable and an oximetry sensor to noninvasively calculate the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate.

The Module works as a component of the Solar Monitoring system and does not function on its own. It provides information obtained from the sensor to the Solar bedside monitor for display of the pulse plethysmographic waveform, the pulse rate and SpO_2 value. The high and low SpO_2 and pulse rate alarm limits, alarms, trends and status messages are all controlled by the bedside monitor.

The SPO2 module contains the electronic hardware and software that receives and calculates the signals from the LEDs to determine the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate and provides for the connection to the connecting cable.

The connecting cable connects the SPO2 module to the oximetry sensors and transfers LED drive power and the collaboration drive to the oximetry sensors from the module and the module receives the detector signal from the oximetry sensor.

Intended Use: The Solar SPO2 Module is intended for use under the direct supervision of a licensed healthcare practitioner. It is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Solar SPO2 Module and accessories are indicated for use with adult, pediatric, and neonatal patients in hospitals and hospital-type facilities.

Technology: The Solar SPO2 Module employs the same fundamental scientific technology as the predicate devices.

Test Summary: The Solar SPO2 Module complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the Solar SPO2 Module:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion: The results of these measurements demonstrated that the Solar SPO2 Module is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 8 2000

Mr. David Wahlig
GE Marquette Medical Systems, Inc.
8200 W. Tower Avenue
Milwaukee, WI 53223

Re: K002957
Solar SPO2 Module with Masimo SET
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: September 21, 2000
Received: September 22, 2000

Dear Mr. Wahlig:

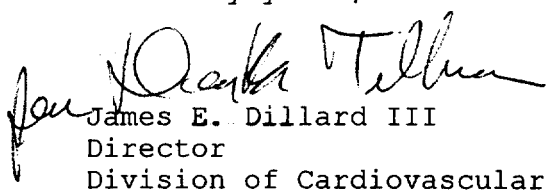
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002957 510(k) filed on October 13, 2000

Device Name: Solar SPO2 Module with Masimo SET

Indications For Use:

The Solar SPO2 Module is intended for use under the direct supervision of a licensed healthcare practitioner. It is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Solar SPO2 Module and accessories are indicated for use with adult, pediatric, and neonatal patients in hospitals and hospital-type facilities.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

K002957

Division of Cardiovascular & Respiratory Devices
510(k) Number